

BAG SYSTEM WITH DEVICE FOR ASSOCIATING SAMPLING RECEPTACLES

PRIORITY CLAIM

The present invention claims priority under 35 U.S.C.
\$119(d) to French Patent Application Serial No. 03/02034,
5 filed February 19, 2003.

FIELD OF THE INVENTION

The invention concerns a bag system for collecting a
biological fluid in which sampling receptacles are
10 associated.

BACKGROUND

Biological fluids such as whole blood must be collected from a donor in a collection bag. To accomplish this, one normally uses a the bag system including in closed circuit, a device for collecting the blood which is in fluid communication with at least one blood collection bag. In addition, the system includes a device for sampling the blood which is intended to receive some of the blood taken. The device normally includes at least one sampling receptacle.

The use of such a sampling device makes it possible to obtain, in each receptacle, a sample of blood intended to be analysed, in particular for carrying out serology, virology and a blood count.

In particular, the bag system may be used by collecting the first millilitres of blood in the sampling device, which has a certain number of advantages. Firstly, this reduces the risk of contamination resulting from the presence of bacteria or other foreign substances on the skin of the donor because the first millilitres of blood collected, which are more likely to be affected by this contamination, are sent into the sampling device rather than into the collection bag. Secondly, this makes it possible to take samples before the collection bag is completely filled and consequently does not waste time. Finally, during the collection, the loss of blood volume for the donor may be compensated for the addition of plasma, resulting in a lower haematocrit reading than if the sampling device were filled after the collection bag, and consequently the count would be incorrect.

One problem which is posed is that of the difficulty in handling known bag systems. This is because the user must position several receptacles in order to obtain the samples, which gives rise to a loss of time.

5 One aim of the invention is in particular to resolve this problem by proposing a bag system in which each sampling receptacle is stored at the device for transferring fluid from the bag system into it, the receptacle then being
10 able to be guided by the operator into the transfer device for collecting a sample.

SUMMARY

The invention includes a bag system for collecting a biological fluid, in particular blood. The system includes a device for collecting the fluid which is in fluid
5 communication with at least one fluid collection bag, and a device for sampling the fluid to be collected which includes at least one sampling receptacle. The sampling device includes a device for transferring the fluid from the bag system into the sampling receptacle or receptacles, in which
10 the transfer device is provided with a device for associating the receptacle or receptacles. The association device is arranged to allow the support of the receptacle or receptacles in a standby position, the guidance of the receptacle or receptacles to a transfer position and, after
15 transfer, the dissociation of the receptacle or receptacles from the bag system.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will emerge during the following description given with reference to the accompanying drawings, in which:

5 FIGURE 1A depicts schematically a bag system for collecting blood which includes a sampling device according to a first embodiment;

10 FIGURE 1B depicts schematically a bag system for collecting blood and separating the blood components which includes a sampling device according to a second embodiment;

 FIGURE 2 depicts schematically the transfer device of the sampling device depicted in FIGURE 1A;

15 FIGURES 3A and 3B depict schematically the transfer device of FIGURE 2 in which a sampling receptacle is disposed respectively in a position at a distance and in a transfer position; FIGURE 3C is a representation similar to FIGURE 3B showing a variant embodiment of the transfer device;

20 FIGURE 4 depicts schematically a bag system for collecting blood which includes a sampling device provided with several transfer devices according to FIGURE 2;

25 FIGURES 5A to 5E depict schematically the transfer device of the sampling device of FIGURE 2, respectively front on, in perspective, in profile, in plan view and in transverse section, the sampling receptacles being in the standby position;

 FIGURES 6A and 6B depict schematically the transfer

device of FIGURE 5 according to a variant embodiment, respectively front on and in profile, the receptacles being in the standby position; FIGURE 6C is a view similar to FIGURE 6B in which a receptacle is in the transfer position.

DETAILED DESCRIPTION

FIGURES 1A and 1B depict bag system 1 including a collection device for collecting fluid from a donor and at least one collection bag 2 intended to receive the fluid collected, in particular blood.

The collection device may consist in particular of needle 3 allowing access to the vein of the donor and cap 4 protecting needle 3. In addition, needle protector 5 may be placed slidably on first tube 6. First tube 6 places collection bag 2 in fluid communication with the collection device.

Bag system 1 also includes a sampling device, which is in fluid communication with collection bag 2 by way of first 6 and second 7 tubes connected at first connector 8 in the form of a three-way junction.

In the embodiments depicted, the sampling device includes sampling bag 9 which is connected to the downstream end of second tube 7. The terms downstream and upstream are defined with respect to the direction of flow of the blood, from the collection device to the bags and sampling device.

The sampling device also includes fluid transfer device 10 which is in fluid communication with collection bag 2 by way of first 6 and second 7 tubes, and possibly third tube 11 connected to second tube 7 at second connector 12 in the form of a three-way junction.

As depicted in FIGURE 2, transfer device 10 includes hollow guide 13, open at front part 14 to allow the insertion of sampling receptacle 15, and hollow needle 16

passing through rear part 17 of the guide, so that a downstream part of needle 16 extends inside guide 13 and an upstream part of needle 16 extends outside guide 13. The downstream segment of hollow needle 16 is enclosed in
5 elastic sheath 18. The upstream segment of hollow needle 16 allows the connection of the transfer device with bag system 1. A fluid communication device or tube is then connected to the upstream segment.

First 19 and second 20 clamps may be situated
10 respectively on first tube 6, downstream of connector 8, and on second tube 7. Clamps 19 and 20 make it possible to orient the flow of fluid collected, either to sampling bag 9, when first clamp 19 is closed while second clamp 20 is open, or to collection bag 2, when second clamp 20 is closed
15 while first clamp 19 is open.

Sampling receptacle 15 is filled with the collected blood contained in sampling bag 9, when receptacle 15 is placed in the transfer position, namely when the downstream end of needle 16 is in fluid communication with the inside
20 of receptacle 15, by perforation of closure element 21 of receptacle 15.

Circuit openers may be provided within bag system 1. In particular circuit opener 22 may be situated on second tube 7 close to first connector 8.

25 As depicted in FIGURE 1B, in order to perform filtration and separation steps as well as the removal of the leukocytes from the various constituents of the blood, collection bag 2 may be in fluid communication, by way of fourth tube 23, with satellite bags 24a-c. Leukoreduction

filter 25 may be situated between collection bag 2 and
satellite bag 24a. Satellite bag 24a may be in fluid
communication with one or more other satellite bags, for
example satellite bag 24a may be in fluid communication with
5 two other satellite bags 24b, c. Clamp 26 may be provided
on fourth tube 23 between collection bag 2 and
leukoreduction filter 25. According to one embodiment,
satellite bags 24a-c may be provided with identification tag
35.

10 According to a first embodiment, transfer device 10 is
provided with a device for associating sampling receptacle
15, as depicted in FIGURE 2. The association device
includes first 27 and second 28 sets of projections
distributed longitudinally on the internal surface of guide
15 13, respectively close to needle 16 of the guide and close
to front part 14 of guide 13. The projections are arranged
so as to be deformable by sliding of receptacle 15 within
guide 13 so as to allow a reversible association of
receptacle 15 inside guide 13, and a sliding of receptacle
20 15 inside guide 13 between a standby position (FIGURE 3A),
at a distance from needle 16, and the transfer position
(FIGURE 3B).

As depicted in FIGURES 2, 3A and 3B, the projections
are flexible, in particular elastic, and are reversibly
25 deformable from a forward inclined position to a rearward
inclined position by contact of receptacle 15 when it slides
inside guide 13 in the front to rear direction. When
receptacle 15 is withdrawn from guide 13, the projections
incline from rear to front so that the receptacle is not
30 dissociated from its closure element 21. In the embodiment

depicted, sampling receptacle 15 includes closure element 21 whose diameter is greater than that of the body of receptacle 15, it is during the passage of closure element 21 that the projections incline in one direction or the other.

According to a variant, depicted in FIGURE 3C, the projections of first set 27 situated close to needle 16 are breakable under the effect of the sliding of receptacle 15 placed in the transfer position. The perforation of closure element 21 is thus visible, and the user may check that the perforation has not taken place prior to the collecting of samples.

As depicted in FIGURE 4, several transfer devices 10, in each of which one sampling receptacle 15 is associated in a dissociable fashion, may be connected to bag system 1 by way of second tube 7 or third tube 11, connected to second tube 7 by second connector 12. Associating several receptacles 15 in a dissociable fashion with several transfer devices 10 has advantages, firstly a saving in time for the person responsible for collecting the fluid because he or she does not need to place receptacle 15 in transfer device 10, and secondly a reduction in the risk of error in traceability of the donations, because this makes it possible to fix traceability labels prior to the collecting of samples, in particular at the time of manufacture.

According to a second embodiment, the association device is arranged to enable the supporting of several receptacles 15 at a distance from guide 13 in a standby position and their sequential guidance in guide 13, as depicted in FIGURES 1B and 5A to 5E.

The association device and the transfer device 10 may be associated by clipping on or welding, or may be moulded in one and the same piece.

5 The association device includes housing 29 associated with guide 13. Housing 29 is provided with skirt 30 in which closure element 21 of receptacles 15 is introduced to allow the longitudinal sliding of receptacles 15 in housing 29 towards guide 13. The internal wall of skirt 30 is provided with projection 31 intended, by interaction with
10 closure elements 21, to prevent the transverse withdrawal of receptacles 15 from housing 29.

Skirt 30 includes an open end disposed opposite a scallop formed in the guide, and an opposite closed end. In the other axis, a first open end is disposed opposite the
15 other end which is open so that the body of receptacle or receptacles 15 extends beyond housing 29.

At the time of manufacture, sampling receptacles 15 are introduced into guide 13 through its open front part 14 so that closure element 21 is situated level with groove 32 in
20 housing 29 so that it may be slid therein.

Cap 33 is then placed on guide 13 making it possible to hold receptacles 15 in housing 29 until the samples are collected by the user of system 1.

25 The housing may be of variable size so as to contain from two to ten receptacles 15. The number of receptacles 15 used varies according to the legislation, in France for example five receptacles 15 are used for carrying out normal analyses.

When samples are collected, the person responsible for collection removes cap 33 from guide 13, makes receptacles 15 slide as far as guide 13, and then introduces them so that, by perforation of closure element 21 of receptacle 15, the downstream end of needle 16 is in fluid communication with the inside of receptacle 15. After receptacle 15 has been filled, the user withdraws it from guide 13. In one example embodiment, cap 33 may be provided with a tamper-evident element, such as a tongue which is broken on first opening, so as to be able to identify the first handling of cap 33.

According to a variant, depicted in FIGURES 6A to 6C, transfer device 10 may slide on the association device, so that it may be placed level with each receptacle 15. When transfer device 10 is placed level with receptacle 15, the user may then move transfer device 10 transversely so that closure element 21 is perforated by needle 16. So that transfer device 10 may slide on the association device, two opposite scallops are then formed in guide 13.

As depicted in FIGURE 1B, transfer device 10 associating several sampling receptacles 15 may be connected to bag system 1 by way of second tube 7 and possibly third tube 11.

With known bag systems for collecting blood, the person responsible for collection must identify, by way of a mark, collection bag 2 and sample receptacle or receptacles 15 corresponding to one and the same donation.

According to the invention, the possibility of error in traceability of these donations is considerably reduced

because sampling receptacle or receptacles 15 and collection bag 2 are associated at the time of manufacture in a dissociable fashion. In addition, upon manufacture, collection bag 2 and sampling receptacle or receptacles 15, as well as satellite bags 24a-c, are each provided with identification tag 35, for example by way of a self-adhesive label with bar codes, which includes information making it possible, after dissociation of the receptacle from bag system 1, to unequivocally establish that sampling receptacle 15 and collection bag 2, as well as any satellite bags 24a-c, come from the same bag system 1.